



FDA U.S. FOOD & DRUG
ADMINISTRATION

March 13, 2019

In Response Refer to File: **2018-9768**

Claire Tighe
Muckrock News DEPT MR 64168
411A Highland Avenue
Somerville, MA 02144

Dear Requestor,

This is in response to your electronic Freedom of Information Act submission, in which you are seeking a copy of the of all available information on any postmarketing summaries and/or postmarketing studies of the Mirena IUS levonorgestrel system as it pertains to the outcome of pseudotumor cerebri, pregnancy, and death. Your request was received in the Center for Drug Evaluation and Research on December 4, 2018.

The releasable document is enclosed

The following charges may be included in a monthly invoice:

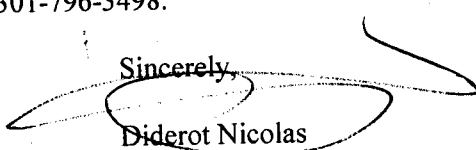
Search: \$23.00 Review: \$0.00 Other: \$1.00 TOTAL: \$24.00

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me at 301-796-3498.

Sincerely,


Diderot Nicolas
Regulatory Counsel
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

If you are not satisfied with any aspect of the processing and handling of this request please contact:

FDA FOIA Liaison
Office of the Executive Secretariat
5630 Fishers Lane Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Enclosure: OSE 2015-2121_Reversible Contraceptive Products_Cases of Death_9-23-2015. (1 CD)

